UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC., PROCUCTS LIABILITY LITIGATION	
	MDL No.: 2419
	Master Docket No.: 1:13-md-2419-FDS
THIS DOCUMENT RELATES TO:	
All Actions Against Specialty Surgery Center And Dr. Kenneth Lister	

PLAINTIFFS' STEERING COMMITTEE' RULE 56.1 COUNTER-STATEMENT OF FACTS IN SUPPORT OF OPPOSITION TO SSC DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

1. To date, more than 750 people suffered fungal meningitis, fungal infections, or abscesses as a result of contaminated steroids originally compounded by the New England Company Center in Framingham, Massachusetts, and at least 64 people died. (Exhibit A to Declaration of Benjamin A. Gastel, *U. S. Centers for Disease Control and Prevention*)[1]

2. Tainted steroids sickened 153 Tennesseeans and killed 16 Tennesseeans. (Exhibit A, *U. S. Centers for Disease Control and Prevention.*

3. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a patient's prescription. (Ex. B, Depo. Exhibit No. 33; *see also* Exhibit C, Defendants' Responses to PSC's 1st Set of Requests for Admissions and Corresponding Interrogatory ("RFAs") with selected exhibits, Response to RFA No. 7 ("Response to RFA No. X")).

[1] Hereinafter, all exhibit references shall be to the corresponding letter exhibit in the Gastel Declaration, unless otherwise noted.

4. Compounded drugs are mixed in response to a physician's prescription in order to create a medication tailored to the specialized needs of an individual patient. (Ex. B, Depo. Exhibit No. 33; *see* Exhibit C, Response to RFA No. 7).

5. Traditional compounding is used typically to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or dilute dosages in children. (Exhibit D, Depo. Exhibit No. 32; Exhibit C, Response to RFA No. 12)

6. Because the law requires that compounding pharmacies compound specific medications in response to individual prescriptions, compounding pharmacies should not produce medications in bulk for mass distribution. (Exhibit D, Depo. Exhibit No. 32; and Ex. C, Response to RFA No. 12).

7. Because compounding pharmacies were not supposed to produce medications in bulk for mass distribution, the FDA did not regulate them to the same degree as pharmaceutical companies. (*See* Exhibit D, Depo. Exhibit No. 32; Exhibit C, Response to RFA No. 12 (and Ex. 4 thereto)).

8. The FDA generally leaves regulation of compounding pharmacies to state pharmacy boards (*See* Exhibit D, Exhibit No. 32, Response to RFA No. 12).

9. In 2002 (ten years before the meningitis catastrophe), the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. That report concluded: "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination. (*See* Exhibit E, Depo. Ex. No. 35; Ex. C, Response to RFA No. 1).

10. On March 24, 2005 (seven years before the meningitis catastrophe), *USA Today* published a front page article with the following headline: "*Safety concerns grow over pharmacy-mixed drugs*." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies. (*See* Exhibit F; and Exhibit C, Response to RFA No. 6).

11. In 2006 (six years before the catastrophe), the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "*poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths*." (*See* Exhibit B, Depo. Ex. No. 33; and Ex. C, Response to RFA No. 7).

12. In May 2007 (five years before the catastrophe), the FDA published an article titled: "*The Special Risks of Pharmacy Compounding*." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice." (*See* Exhibit D, Depo. Ex. No. 32; and Exhibit C, Response to RFA No. 7 (and Ex. 4 thereto).)

13. In 2010 (two years before the catastrophe), the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs. (*See* Exhibit C, Response to RFA No. 17.)

14. On November 5, 2010 (about two years before the catastrophe), the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and

other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
> . . .
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

(*See* Exhibit G (joint report); Exhibit C, Response to RFA No. 18.)

15. In May 2012 (a few months before the meningitis catastrophe), the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products." (Exhibit H (report); Exhibit C, Response to RFA No. 19.)

16. NECC was the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy that often focused on unsterile conditions at NECC's facilities. (*See* Exhibit I; The Committee on Energy and Commerce Majority Memorandum Re: Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?", pp. 6 – 25).)

17. In 2006, the FDA issued a warning letter to NECC, detailing numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, the compounding of commercially available drugs, the selling of misbranded drugs, and problems with storage and sterility. (*See* Exhibit J, Depo. Exhibit No. 306.)

18. The Defendants operated a high volume pain clinic that distributed hundreds of vials of Depo-Medrol to patients each year. (Exhibit K, Depo. Exhibit No. 99, **Filed Under Seal**; Exhibit L, Depo. Exhibit No. 100, **Filed Under Seal**; Exhibit M, Excerpts of Jean Atkinson Deposition ("Atkinson Dep.") at 29-30; 46-53; Exhibit N, Excerpt of Deposition of Jeffrey Ebel ("Ebel Dep.") at 14; Exhibit O, Excerpts of Deposition of Dr. Kenneth Lister ("Lister Dep.") at 133-34.)

19. In 2012, Dr. Kenneth Lister, a part owner of SSC, performed as many as 14 epidural steroid injections per day at SSC. (Exhibit O, Lister Dep. at 204.)

20. In 2012, Jean Atkinson was the Director of Nursing for SSC. (Exhibit M, Atkinson Dep. at 78:5-6.)

21. In 2012, defendant Calisher & Associates performed management services for SSC. (Exhibit P, Excerpts of Deposition of Gina Calisher as 30(b)(6) Representative for Calisher & Associates ("Calisher Dep."), at 18-19.)

22. In July 2012, SSC switched to purchasing compounded MPA from NECC, and SSC, Dr. Lister, and Calishers all participated in that decision. (Exhibit M, Atkinson Dep. at 38-39, 78:14-19; 94:5-95:1; 107-108; Exhibit O, Lister Dep. 128; 136; 190-91).

23. When SSC switched to purchasing compounded MPA from NECC in July 2012, SSC, Dr. Lister, nor Calishers did any of the following:

a. Investigate whether NECC had any regulatory actions against them because of previous problems;

b. Investigate NECC had a history of producing contaminated products;

c. Investigate whether anyone state or federal agencies had made any complaints or taken any actions against NECC ;

d. Contact the Tennessee Department of Health about NECC;

e. Contact any state board of pharmacy about NECC;

f. Consult with experts or attorneys concerning regulatory compliance issues, the safety of compounding pharmacies, and the legality of purchasing from them in bulk;

g. Research the differences between compounded pharmacies and FDA-licensed distributors;

h. Conduct a Google search of NECC;

i. No attempt to visit NECC's facilities;

j. No review of FDA publications and warnings, media articles, or medical literature regarding the dangers of compounded drugs.

k. No research concerning the safety and risks of compounded medications;

l. No effort to verify information contained in NECC promotional literature.

(*See* Exhibit M, Atkinson Dep. at 41, 64-68, 76); Exhibit O, Lister Dep. at 136-38; Exhibit P, Calisher Dep. at 27, 32-33, 90-92)

24. In 2012, SSC did not subscribe to any medical journals. (Exhibit O, Lister at 56:5-7.)

25. Prior to July 2012, SSC purchased Depo-Medrol from Besse Medical and CuraScript, both of which sold only FDA-approved pharmaceuticals. (Exhibit K, Depo. Exhibit No. 99, **Filed Under Seal**; Exhibit L, Depo. Exhibit No. 100, **Filed Under Seal**; Exhibit M, Atkinson Dep. at 29-30; 46-53; Exhibit N, Ebel Dep. at 14; Exhibit O, Lister Dep. at 133-34).

26. Prior to July 2012, SSC had never purchased steroids for use in epidural steroid injections from compounding pharmacies. (Exhibit O, Lister Dep. at 133-134.

27. In July 2012, SSC chose to stop purchasing FDA-approved steroids through Besse Medical and CuraScript, and started purchasing compounded MPA in bulk from NECC. (Exhibit M, Atkinson Dep. at 58.)

28. Prior to the September 2012 fungal meningitis outbreak, SSC was always able to obtain Depo-Medrol for its patients, and never had to cancel a patient's scheduled procedure because Depo-Medrol was unavailable. (Exhibit O, Lister Dep. at 132; Exhibit M, Atkinson Dep. at 45)

29. Prior to SSC's switch to purchasing compounded MPA from NECC, Calishers did not contact any pharmaceutical wholesalers to determine whether a sufficient supply of Depo-Medrol in fact was unavailable. (Exhibit P, Calishers Dep. at 33.)

30. According to internal SSC records, SSC purchased from NECC because it offered a "good price" for its compounded MPA. (Exhibit Q, SSC-07622-23, **Filed Under Seal**).

31. According to invoices produced by SSC, the clinic purchased hundreds of vials of MPA from NECC between July 2012 and September 2012. (Collective Exhibit R, Depo. Exhibit Nos. 93 and 94.)

32. SSC made its bulk purchases of MPA from NECC without filling out a valid patient-specific prescription for each patient who received an injection of NECC-compounded MPA. (Exhibit M, Atkinson Dep. at 104-106; 113; Exhibit O, Lister Dep. at 199)

33. The Defendants operated a for-profit corporation. (Exhibit S, Excerpts from Kimberly Bowlin Deposition ("Bowlin Dep.") at 26:17-10.)

34. When the Defendants performed an epidural steroid injection, they expected to be paid for each injection. (Exhibit S, Bowlin Dep. at 26:21-25.)

35. In the Summer of 2012, Dr. Lister was the only doctor at the Special Surgery Center who performed epidural steroid injections. (Exhibit S, Bowlin Dep. at 27:22-25.)

36. The Defendants provided epidural steroids to patients in exchange for money. (Exhibit S, Bowlin Dep. 27:14-17.)

37. Dr. Lister received payment for each epidural steroid injection that he performed, separate and part from money that was paid to SSC for each injection. (Exhibit O, Lister Dep. at 28-29)

38. In 2012, Dr. Lister performed approximately 40 to 60 epidural steroid injections per month. (Exhibit O, Lister Dep. at 104.)

39. Dr. Lister's pain management services, about half of which constituted epidural steroid injections, represented approximately one-third of SSC's procedure volume between January 2012 and September 2012. (Exhibit O, Lister Dep. at 103)

40. When SSC administered epidural steroid injections to patients, SSC charged patients for the injection separately from the services of Dr. Lister, the physician who injected the medicine. (Exhibit O, Lister Dep. at 34-35; 65; 121)

41. With respect to SSC's charges associated with each epidural steroid injection, SSC charged patients a fee that included charges for the steroid itself. (Exhibit O, Lister Dep. at 34; 65-66)

42. SSC received the same reimbursement from insurance companies for epidural steroid injections regardless of how much SSC paid for the underlying steroid. (Exhibit O, Lister Dep. at 122-123)

43. If SSC paid less for a steroid product, it would have retained more of the reimbursement amount associated with an epidural steroid injection. (Exhibit O, Lister Dep. at 123)

44. After SSC began purchasing MPA from NECC with Dr. Lister's knowledge, Dr. Lister did not inform any of his patients injected with that MPA that it had been purchased from a compounding pharmacy. (Exhibit O, Lister 127)

45. Dr. Lister did not tell of the patients into whom he injected NECC MPA that the product did not contain preservatives. (Exhibit O, Lister Dep. at 127)

Date: July 20, 2016

Respectfully submitted:

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CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: July 20, 2016

/s/ Benjamin A. Gastel
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